## **Morgan Lewis**

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December 12, 2024

## VIA CM/ECF

Honorable Jennifer L. Hall J. Caleb Boggs Federal Building 844 N. King Street Wilmington, DE 19801-3555

Re: Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., C.A. No. 21-1015-JLH

Dear Judge Hall:

I write on behalf of Plaintiffs Nippon Shinyaku Co. Ltd. and NS Pharma, Inc. (collectively, "NS") concerning the Court's suggestion concerning bifurcation of next week's trial (D.I. 669 at 4) and in response to Sarepta's unsolicited letter (D.I. 670) "offer[ing] . . . thoughts to the extent they are helpful to the Court's consideration of the issue."

NS does not believe that bifurcation will simplify the issues and proposes the trial go forward as scheduled, with a verdict form that requires the jury to provide a reasonable royalty amount even if the jury also awards lost profits for either party. This will allow for post-trial briefing on the cross-lost profits issue, if it remains live.

NS's primary concern with bifurcation is that it is likely to unnecessarily lengthen the trial, potentially requiring the Court to impanel a new jury to decide damages. In three of the four scenarios Sarepta proposes, the jury will have to decide some questions related to damages. But if the jury is asked to deliberate first as to validity, there may not be sufficient time left for (1) the Court to decide how to proceed (including potentially deciding the cross-lost profits issue), (2) the parties to present their damages cases (presumably with openings and closings), (3) the Court to instruct the jury, and (4) the jury to deliberate. In Sarepta's fourth scenario—both patents are invalid—this case is no different from any other case with validity challenges at trial, where bifurcation is the exception rather than the rule.

As the Court is well-aware, Sarepta raised its "no cross-lost profits" argument for the first time to NS the evening before the pretrial conference and to the Court at the pretrial conference. Sarepta's challenges have long been forfeited. A forfeited issue should not dictate how the trial proceeds.

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Finally, Sarepta cites a case in its letter that supports NS's position that there is nothing improper with the award of cross-lost profits. *See Medtronic Vascular Inc. v. Abbott Cardiovascular Sys., Inc.*, 2009 WL 1421632, at \*4 (N.D. Cal. May 15, 2009). In *Medtronic* the Court said that while the argument that there cannot be lost profits for plaintiff because the defendant was already awarded lost profits in a separate action pending on appeal is "appealing at first blush," but "there are significant problems." *Id.* The court focused on the non-final nature of the defendants' lost profits award that was on appeal as well as the lack of any injunction.

This Court relied on *Medtronic* in *Cordis Corp. v. Boston Sci. Corp.*, 2009 WL 3160270, at \*4 (D. Del. Sept. 30, 2009), explaining: "BSC asserts that Cordis is not entitled to claim any lost profits, now that it has been determined to infringe the Jang '021 patent. . . . I conclude that BSC's argument in this regard has neither a basis in law nor in fact, given that Cordis' Cypher stent is still on the market." *Id*.

Applying the reasoning in *Medtronic* and *Cordis* to the analogous facts here, this case should proceed to trial as NS proposes.

Respectfully submitted,

/s/ Amy M. Dudash

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cc: All Counsel of Record (via CM/ECF)